FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

MYLAN DEFENDANTS' SUPPLEMENTAL BRIEF

Mark Kenny, the only expert witness for Plaintiffs who said anything about Mylan, did not and cannot identify any legal duty with which Mylan allegedly failed to comply. Mr. Kenny concedes that, as a wholesale distributor of Digitek®, Mylan had no duty under federal cGMP regulations to do any of the things he claimed it failed to do.[1] Further, Mr. Kenny's opinions fail to satisfy *Daubert* and should be excluded because: (1) Mr. Kenny does not have expertise in the critical areas of pharmaceutical distribution and regulation;[2] (2) his opinions are a litigation-driven afterthought, added at the urging of Plaintiffs' Counsel and a phantom "co-expert"[3]; (3) his methodology is flawed (e.g., he did not bother to review Mylan's quality control records);[4] and (4) his conclusion that Mylan would have detected cGMP issues affecting Digitek® before the FDA amounts to rank speculation.

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1 Despite the fact that the federal regulations do not impose a duty on wholesale distributors to establish a so-called "quality agreement" with or to conduct audits of a finished-product manufacturer, they form the wobbly foundation for Mr. Kenny's opinion that Mylan's quality control system over outside manufacturers was lacking. *See* Pla. Ex. 511 at 33.

2 Pla. Ex. 509 at 181:12-182:5; Pla. Ex. 510 at 329:25-330:12.

3 Mylan Defs.' Reply 1-2.

4 *Id*. at 6-7; Pla. Ex. 511 at 33-34, 41-42 (containing no reference to Mylan's internal Quality Assurance policies and procedures for outsourced products (i.e., finished products purchased from outside manufacturers)).

Because Plaintiffs cannot establish the existence or breach of any legal duty by Mylan—either by reference to specific federal regulations or reliable expert testimony[5]—these claims must be dismissed. The remaining derivative claims against Mylan should also be dismissed for the reasons set forth in Mylan's Companion Motion for Summary Judgment, Defendants' Motion for Summary Judgment and their related briefs.

Respectfully submitted,

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[5] Reliable expert testimony is necessary to assist the jury in understanding the standard of care under which pharmaceutical wholesale distributors, like Mylan, operate. *See, e.g., Federal Rule of Evidence 702; In re Fosomax Products Liability Litigation*, 2009 U.S. Dist. LEXIS 64661, *68 (S.D.N.Y. 2009) ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry).

CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2011, a copy of the foregoing Mylan Defendants Reply in Support of Companion Motion to Exclude Expert Testimony was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Respectfully submitted,

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